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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,229	06/25/2001	Richard Ian Christopherson	DAVI139.001A	2287

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,229	CHRISTOPHERSON ET AL.	
	Examiner	Art Unit	
	Cheyne D. Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 08, 2005 has been entered.

2. Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

3. Claims 58-71 are examined on the merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER REJECTION

5. Claims 58-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claim 58, line 5, recites the limitation of "on the same cell" which is not disclosed in the pointed to support. It is noted that page 11, lines 25-27, disclose "the surface of normal cells or cancer cells..." which is different from the new limitation of "on the same cell." The same issue is present in claims 59, 62, 63, and 65.

ENABLEMENT REJECTION

7. Claims 58-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a device for determining the presence of cancer or a propensity to develop cancer in an animal as directed to the different cell surface antigens from a population of cells such as CCRF-CEM T cell leukemia and Raji B cell lymphoma, does not reasonably provide enablement for an invention that is beyond the cancers cited above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

8. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

9. It is noted that Applicant has provided enablement disclosure for the claimed invention as directed to CCRF-CEM T cell leukemia and Raji B cell lymphoma wherein the cancers are characterized by the specific combination of CDs (page 61). However, Applicant does not disclose the specific combination of CDs required for diseases beyond the disclosed CCRF-CEM T cell leukemia and Raji B cell lymphoma (page 61). It is noted that Applicant has asserted that the instant invention is applicable to the diagnosis of lupus, cancer, autoimmune disease, and AIDS (pages 22-25). However, Applicant has not disclosed the required CDs that are being utilized to diagnose the diseases described on pages 22-25. For example, on page 61, Applicant discloses the specific combination of CCRF-CEM T cell leukemia and Raji B cell lymphoma. Further, Applicant discloses

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in the discussion directed to well known in the art method for disease diagnosis that expression of specific CD is one of four criteria that are currently used to diagnose acute myeloid leukemia (AML) (pages 2-3). The disclosure has been reasonably construed as each disease has a specific combinations of surface markers wherein the expression pattern corresponding to said markers is being utilized for diagnosis of said each disease. The instant specification does not disclose the required specific CDs to practice the claimed invention as commensurate in scope with the instant claims. Therefore, undue experimentation would be required from one of skill in the art to predictably practice the claimed invention as directed to cancers beyond the disclosed CCRF-CEM T cell leukemia and Raji B cell lymphoma.

10. Further, as discussed above, Applicant discloses in the discussion directed to well known in the art method for disease diagnosis, wherein four criteria, morphology, expression of specific CD, lymphoid (LY) and myeloid (MY) antigens, enzyme activities and cytogenetic abnormalities, such as chromosome translocations, are currently used to diagnose acute myeloid leukemia (AML) (pages 2-3). The disclosure supports that CDs is not relied on solely for diagnosis. Further, the expression of specific CD with three other criteria are necessary for the diagnosis of AML. However, the instant invention requires only CD expression as the sole basis for the instant invention. Therefore, the lack of disclosure directed to the expression of specific CD beyond the disclosed CDs for CCRF-CEM T cell leukemia and Raji B cell lymphoma, and the lack of requirement of

criteria beyond CDs expression support that undue experimentation would be required from one of skill in the art to predictably practice invention as claimed.

CLAIM REJECTIONS - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 58-62, 65, 66, and 68-70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yoshinari et al. (1996).

RESPONSE TO ARGUMENTS

13. Applicant's argument Yoshinari et al. fails to teach or suggest an assay device that comprises a solid support to which an array of immunoglobin molecules are immobilized is unpersuasive because Yoshinari et al. describes an ELISA device comprising an array of the four MAbs selected from the screening with A549 lung adenocarcinoma cells in 96-well microplates (immobilized in discrete regions) wherein said MAbs react to different surface antigens. It is noted that the limitation of "array" has not been specifically defined in the instant specification. Therefore, the cited disclosure is consistent with the required limitation as exemplified by the instant specification.

14. Applicant argues that Yoshinari et al. also fail to teach that the array of immunoglobin molecules is contacted by a biological sample that comprises a cell, which expresses different cell surface antigens that interact with different immunoglobin molecules that comprise the array. Further, Applicant argues "Yoshinari et al. simply do not teach...an array of different immunoglobins are immobilized, which bind to different cell surface antigens on the same cell. Applicant's arguments are not persuasive. Yoshinari et al. discloses via Table II (page 363) 28K29, 27D57 and ZLG40 recognize A549 cell surface antigen, and Mab (29D38) recognized nuclear membrane antigen of the same cell line (page 363, column 2, 25-42). Yoshinari et al. supports that the MAbs bind to different surface antigens by performing antigen immunoblotting wherein MAbs 28K29 and ZLG40 reacted with bands of approximately 600,000 and 50,000, respectively. The Mab 2938 bound to one or more substances more than 1,000,000 (page 364, column 2, to page 365, column 1, Antigen Immunoblotting §). The citation above supports that the antibodies of Yoshinari et al. is specific for different surface antigen on the same cell.

15. Further, Applicant argues Yoshinari et al. "fails to teach or suggest that the interactions between the array of immunoglobin molecules and the cell surface antigens enable simultaneous detection of a differential pattern of density indicative of the presence of cancer. It is noted that the claims do not recite the limitation of "enable simultaneous detection of a differential pattern of density indicative of the presence of cancer." Further, claims 59, 62, and 65 recite an assay device wherein the limitations after the term "when" are directed a condition which does not structurally limit the claimed device. Further, said

limitations are directed to the inherent properties of said device wherein the cited prior art device reasonably possesses said inherent properties to fulfill the condition described after the term "when" in said claims. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

BASIS FOR REJECTION

16. Yoshinari et al. describes an ELISA device comprising an array of the four MAbs selected from the screening with A549 lung adenocarcinoma cells in 96-well microplates (immobilized in discrete regions) wherein said MAbs react to different surface antigens. The two controls show no reactivity to the cells (page 363, column 1, Results §). Yoshinari et al. discloses via Table II (page 363) 28K29, 27D57 and ZLG40 recognize A549 cell surface antigen, and Mab (29D38) recognized nuclear membrane antigen of the same cell line (page 363, column 2, 25-42). Yoshinari et al. supports that the MAbs bind to different surface antigens by performing antigen immunoblotting wherein MAbs 28K29 and ZLG40 reacted with bands of approximately 600,000 and 50,000, respectively. The Mab 2938 bound to one or more substances more than 1,000,000 (page 364, column 2, to page 365, column 1, Antigen Immunoblotting §), claims 58-60, 62, 65, 66, 68, and 70.

17. The assay device of Yoshinari et al. detects surface antigens from myeloma cell line (page 359, column 2, last paragraph), as in instant claim 61.

18. The device of Yoshinari et al. is applicable to cells from mouse or human (page 359, last paragraph), as in instant claim 69.

19. Claims 59, 62, and 65 recite an assay device wherein the limitations after the term "when" are directed a condition which does not structurally limit the claimed device. Further, said limitations directed to the inherent properties wherein the cited prior art device reasonably possesses said inherent properties to fulfill the condition described after the term "when" in said claims. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the< claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

20. It is noted that claims 60, 66, 68, and 70 have been rejected because said claims further limit limitations that do not structurally limit the claimed in regard to the prior art.

CONCLUSION

21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

22. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

23. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly
6/26/05

Ardin H. Marschel 6/27/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER